

FORM 1449°

Docket Number

30436.57USU1

Application Number

09/865,321

Applicant

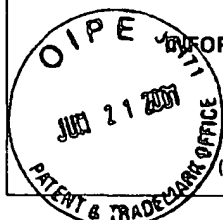
Robert J. Peach et al.

Filing Date

May 23, 2001

Group Art Unit

Not yet known



INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
24/2	5,637,481 (Exhibit 1)	6/10/97	Ledbetter et al.			9/13/93
	5,773,253 (Exhibit 2)	6/30/98	Linsley et al.			7/21/95
	5,844,095 (Exhibit 3)	12/1/98	Linsley et al.			1/18/95
	5,851,795 (Exhibit 4)	12/22/98	Linsley et al.			6/2/96
	5,885,579 (Exhibit 5)	3/23/99	Linsley et al.			7/8/97
	5,885,796 (Exhibit 6)	3/23/99	Linsley et al.			7/8/97
	5,958,403 (Exhibit 7)	9/28/99	Strom et al.			7/11/94
	5,968,510 (Exhibit 8)	10/19/99	Linsley et al.			10/4/96
24/2	5,977,318 (Exhibit 9)	11/2/99	Linsley et al.			6/7/95

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	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
24/2	EP 757,099 (Exhibit 10)	5/2/97	Europe				X
	WO 93/00,431 (Exhibit 11)	1/7/93	PCT				X
	WO 95/01,994 (Exhibit 12)	1/19/95	PCT				X
	WO 95/33,770 (Exhibit 13)	12/14/95	PCT				X
	WO 97/28,267 (Exhibit 14)	8/7/97	PCT				X
	WO 97/37,687 (Exhibit 15)	10/16/97	PCT				X
	WO 97/47,732 (Exhibit 16)	12/18/97	PCT				X
	WO 98/31,820 (Exhibit 17)	7/23/98	PCT				X
	WO 98/33,513 (Exhibit 18)	8/6/98	PCT				X
	WO 99/29,883 (Exhibit 19)	6/17/99	PCT				X
	WO 99/47,558 (Exhibit 20)	9/23/99	PCT				X
	WO 99/49,734 (Exhibit 21)	10/7/99	PCT				X
	WO 99/51,275 (Exhibit 22)	10/14/99	PCT				X
24/2	WO 99/57,266 (Exhibit 23)	11/11/99	PCT				X

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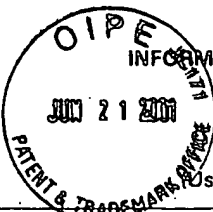
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*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FORM 1449°  INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number 30436.57USU1	Application Number 09/865,321
	Applicant Robert J. Peach et al.	
	Filing Date May 23, 2001	Group Art Unit Not yet known

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	Lenschow et al. (1992) Science 257: 789-792 (Exhibit 25)
	Linsley et al. (1992) Science 257: 792-795 (Exhibit 26)
	Linsley et al. (1992) J. Exp. Med. 176:1595-1604 (Exhibit 27)
	Tan et al. (1993) J. Exp. Med. 177:165-173 (Exhibit 28)
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	Guo et al. (1995) J. Exp. Med. 181:1345-1355. (Exhibit 35)
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212	Pearson et al. (2000) Transplantation 69:S-123. (Exhibit 52) (Abstract #44)
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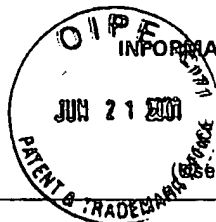
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1646

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EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLAS S	FILING DATE IF APPROPRIATE
JN2	5,434,131 (Exhibit 58)	7/18-95	Linsley, et al.	 	 	5/26/93
	5,770,197 (Exhibit 59)	6/23/98	Linsley, et al.	 	 	1/22/93
	6,132,992 (Exhibit 60)	5/5/95	Ledbetter et al.	 	 	10/17/00
	6,090,914 (Exhibit 61)	7/18/00	Linsley, et al.	 	 	4/15/94
	5,916,560 (Exhibit 62)	6/29/99	Larsen et al.	 	 	3/20/97
JN	5,993,800 (Exhibit 63)	11/30/99	Linsley, et al.	 	 	6/6/95

FOREIGN PATENT DOCUMENTS

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						YES	NO
JN2	WO 97/34,633 (Exhibit 64)	3/20/97	PCT	 	 		X

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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U.S. PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLAS S	TRANSLATION	
						YES	NO
<i>JNR</i>	WO 95/33770 (Exhibit 105)	December 14, 1995	PCT				X
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		Blazar et al., 1994 <i>Blood</i> "In Vivo Blockade of CD28/CTLA4: Interaction With CTLA4-Ig Reduces Lethal Murine Graft-Versus-Host Disease Across the Major Histocompatibility Complex Barrier in Mice" 83:3815-3825. (Exhibit 72)					
		Finck et al., <i>Science</i> "Treatment of Murine lupus with CTLA4Ig" 265:1225-1227. (Exhibit 73)					
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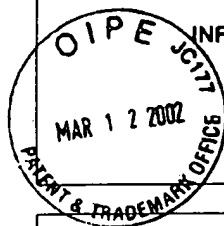
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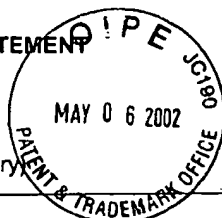
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FOREIGN PATENT DOCUMENTS						
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLAS S	TRANSLATION YES NO
JH	WO 02/02638 A2 (Exhibit 138)	1/10/02	PCT			X
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JH		Becker, J.C., March 8, 2001, Abstract and of Presentation of "A multi-center, randomized, double-blind, placebo controlled study to evaluate the safety and preliminary clinical activity of multiple doses of CTLA4Ig and LEA29Y administration intravenously to subjects with rheumatoid arthritis," presented at American College of Rheumatology Conference: "2001 Innovative Therapies in Autoimmune Diseases," San Francisco, California (Exhibit 114)				
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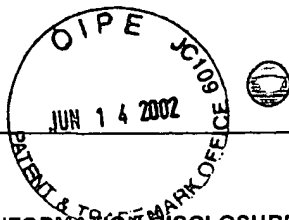
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	Filing Date May 23, 2001	Group Art Unit 1646
	MAY 06 2002 PATENT & TRADEMARK OFFICE	

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EXAMINER <i>[Signature]</i>	DATE CONSIDERED <i>1/20/04</i>
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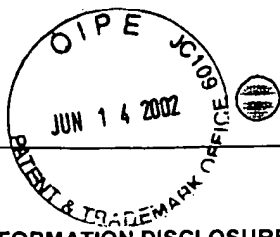
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			Pearson, Thomas C., et al., "ANALYSIS OF THE B7 COSTIMULATORY PATHWAY IN ALLOGRAFT REJECTION ¹ ," <i>Transplantation</i> , 1997, 63:1463-1469. (Exhibit 140)				
			Pearson, Thomas C., et al., "TRANSPLANTATION TOLERANCE INDUCED BY CTLA4-Ig ¹ ," <i>Transplantation</i> , 1994, 57:1701-1706. (Exhibit 141)				
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			Elwood, Eric T., et al., "Microchimerism and rejection in clinical transplantation," <i>The Lancet</i> , 1997, 349:1358-1360. (Exhibit 148)				
		Larsen, Christian P., and Thomas C. Pearson., "The CD40 pathway in allograft rejection, acceptance, and tolerance," <i>Transplantation</i> , 1997, 9:641-647. (Exhibit 149)					
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		Bingaman, Adam W., et al., "Vigorous Allograft Rejection in the Absence of Danger ¹ ," <i>Journal of Immunology</i> , 2000,164:3065-3071. (Exhibit 154)
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		Durham, Megan M., et al., "Cutting Edge: Administration of Anti-CD40 Ligand and Donor Bone Marrow Leads to Hemopoietic Chimerism and Donor-Specific Tolerance Without Cytoreductive Conditioning ¹ ," <i>Cutting Edge</i> , 2000,165:1-4. (Exhibit 156)
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		Ha, Jongwon., et al., "Aggressive skin allograft rejection in CD28 ^{-/-} mice independent of the CD40/CD40L costimulatory pathway," <i>Transplant Immunology</i> , 2001, 9:13-17. (Exhibit 162)
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		Ritchie, SC., et al., "Regulation of Immunostimulatory function and B7 molecule expression on murine dendritic cells," <i>Journal of Cellular Biochemistry</i> , 1995, 21A:C1-215 (Exhibit 166)
212		Alexander, DZ., et al., "Analysis of the mechanisms of CTLA4-Ig plus bone marrow induced transplantation tolerance," <i>Journal of Cellular Biochemistry</i> , 1995, 21A:C1-301 (Exhibit 167)

EXAMINER <i>[Signature]</i>	DATE CONSIDERED 11/20/07
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IN AN APPLICATION**

(Use several sheets if necessary)

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Robert J. Peach et al.

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Alexander, DZ., et al., "CTLA4-Ig induced transplantation tolerance: analysis of donor cell chimerism," *Surgical Forum*, 1994, 45:402-403 (Exhibit 168)

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Pearson, TC., et al., "CTLA4-Ig plus bone marrow induces transplantation tolerance in the murine model," *Journal of Cellular Biochemistry*, 1995, 21A:C1-327 (**Exhibit 169**)

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Lakkis, FG., et al., "CTLA4Ig induces long-term cardiac allograft survival in the absence of interleukin-4," *Journal of the American Society of Nephrology*, 1996, 7:A3204 (Exhibit 170)

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					YES NO

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JTY ²	L104EA29Y (Figure 7, of the subject application) was provided to researchers at Emory University, subject to use restrictions and confidentiality by agreement, more than one year before the priority date of the subject application, i.e. May 26, 2000, for use in animal studies in the U.S.
	L104EA29Y (Figure 7 of the subject application) has been the subject of human clinical trials under the direction and control of Bristol-Myers Squibb Company. L104EA29Y was given to investigators who were involved in the clinical trials subject to use restrictions and confidentiality by agreement. L104EA29Y was administered intravenously to human patients in clinical trials.
	L104EA29Y was first administered intravenously to a human patient as early as November 30, 1998 in Scotland
	L104EA29Y was first administered intravenously to a human patient as early as April 24, 1999 in the United States.
	A letter dated July 9, 1998 including a report, submitted to the U.S. Food and Drug Administration in connection with an Investigational New Drug (IND) application, is enclosed as Exhibit 171.
	The letter and report are confidential and were provided confidentially, pursuant to 21 C.F.R. §20.111 or §21 C.F.R. §312.130, to the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration in connection with the Investigational New Drug Application.
	The enclosed letter and report are redacted versions of what were sent to the U.S. Food and Drug Administration.
	The report contained the sequence for BMS-224818 (Figure 3 at page 13 of Exhibit 171), which differs from CTLA4Ig at two amino acid residues, Leu₁₀₄-Glu and Ala₂₉-Tyr (Exhibit 171 at page 2)
JWL	An Investigator Brochure dated January 26, 1999 is enclosed as Exhibit 172.

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~~The Investigator Brochure is confidential and was provided to investigators who were involved in the clinical trials and subject to confidentiality by agreement, more than one year before the priority date of the subject application, i.e. May 26, 2000.~~

The enclosed Investigator Brochure is a redacted version of what was sent to investigators.

The Investigator Brochure contained a text description and a schematic representation of IEA29Y (Figure 1 at page 6 of Exhibit 172), but not the sequence of L104EA29Y (Figure 7, of the subject application).

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JNR	5,770,197 (Exhibit 182)	June 23, 1998	Peter S. Linsley et al.	<div style="font-size: 4em;">X</div>	<div style="font-size: 4em;">X</div>	January 22, 1993
	6,132,992 (Exhibit 183)	October 17, 2000	Jeffrey A. Ledbetter et al.			October 5, 1995
	6,090,914 (Exhibit 184)	July 18, 2000	Peter S. Linsley et al.			July 18, 2000
	5,977,318 (Exhibit 185)	November 2, 1999	Peter S. Linsley et al.			June 7, 1995
	5,885,579 (Exhibit 186)	March 23, 1999	Peter S. Linsley et al.			July 8, 1997
	5,993,800 (Exhibit 187)	November 30, 1999	Peter S. Linsley et al.			June 6, 1995
JNR	5,916,560 (Exhibit 188)	June 29, 1999	Christian P. Larsen et al.			March 20, 1997

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						YES NO
JNR	EP 0 613 944 A2 (Exhibit 173)	September 7, 1994	EPO	<div style="font-size: 4em;">X</div>	<div style="font-size: 4em;">X</div>	X
	EP 0 682 039 A1 (Exhibit 174)	November 15, 1995	EPO			X
	WO 98/56417 (Exhibit 175)	December 17, 1998	PCT			X
	WO 01/92337 (Exhibit 180)	December 6, 2001	PCT			X
JNR	WO 95/34320 (Exhibit 176)	December 21, 1995	PCT			X

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JNR		Sun, Hong et al., "Prevention of Chronic Rejection in Mouse Aortic Allografts by Combined Treatment with CTLA4-Ig and Anti-CD40 Ligand Monoclonal Antibody," Transplantation, 1997, 64:1838-56 (Exhibit 177)
JNR		Souza, "Synergistic inhibition of established collagen induced arthritis (CIA) through dual inhibition of ICAM-1 and CD40L pathways," Arthritis and Rheumatism, 1999, page S60; abstract 64 (Exhibit 178)

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